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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,480	02/26/2004	Daniel P. Silver	20363-011 CON	8561

7590 09/12/2007

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EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	**PAPER NUMBER**
1636	

MAIL DATE	DELIVERY MODE
09/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,480	SILVER ET AL.	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *1-5,7-11 and 26-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 12-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 June 2007 has been entered.

This Office Action is a reply to the Paper filed 13 June 2007 in response to the Final Office Action mailed 27 December 2006. Claims 1-5, 7-11 and 26-34 were withdrawn from consideration and claims 6 and 12-25 were considered in the 5 May Office Action. Claims 6, 14, 15, 18, 19, 20 and 25 were amended in the 7 August Paper. Claims 1-34 are pending and claims 6 and 12-25 are under consideration.

Response to Amendment and Arguments

Claim Rejections - 35 USC § 112

Rejection of claims 6 and 12-25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the antecedent basis for the limitation "said recombinase" is unclear is **withdrawn** in view of the claim amendments.

Rejection of claims 6 and 12-25 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation, "the signal sequences for the first nucleic acid and the second nucleic acid are not the same sequences" is also **withdrawn**. Upon further consideration and a review of

the application (particularly page 7, lines 23-25) it is clear that the signal sites can comprise the same or different sequence so long as they are not "the very same signal sites used to modify the target".

Claim Rejections - 35 USC § 102

Rejection of claims 6, 12, 17-23 and 25 under 35 U.S.C. 102(a or e) as being anticipated by Hodges *et al.*, US Patent No. 5,929,307 is **withdrawn** in view of the amendment of the claims such that they now require that the recombinase encoded by the recombinase gene of the first nucleic acid molecule recognize both the signal sequences of the first nucleic acid molecule and the signal sequences of the second nucleic acid molecule.

New Grounds

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6, 12, 13, 14, 17, 21, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baszczynski et al. US Patent No. 6,187,994 in view of Qin et al. (1994) *Proc. Natl. Acad. Sci. USA* 91:1706-1710.

The claims are directed to a method for modulating a target gene in a cell comprising introducing into the cell a first nucleic acid comprising a recombinase gene operably linked to an expression control sequence and signal sequences recognized by a recombinase encoded by the recombinase gene and a second nucleic acid molecule comprising a target gene and signal sequences recognized by the recombinase encoded by the first nucleic acid molecule. The method further requires that the recombinase encode by the recombinase gene in the first nucleic acid molecule, when expressed in the cell, excises a sequence in the first nucleic acid molecule located between the signal sequences, which excision results in modulation of expression of the recombinase gene. In addition, the method requires that the recombinase encoded by the recombinase gene in the first nucleic acid molecule, when expressed in the cell, excises a sequence in said second nucleic acid molecule that is located between the signal sequences in the

second nucleic acid molecule and the excision results in modulation of expression of the target gene. Finally, the claims require that the signal sequences for the first and second nucleic acid are not the same sequences.

Baszczynski et al. teaches a method of introducing a nucleic acid into a plant genome comprising first introducing a nucleotide sequence flanked by two non-identical recombination sites (hereinafter referred to as the "first nucleic acid molecule") into the target organism's genome and establishing a target site for insertion of nucleotide sequences of interest. According to the method of Baszczynski et al., once a stable plant or cultured tissue is established a second construct, or nucleotide sequence of interest, flanked by corresponding recombination sites as those flanking the target site (hereinafter referred to as the "second nucleic acid molecule"), is introduced into the stably transformed plant or tissues in the presence of a recombinase protein resulting in exchange of the nucleotide sequences between the non-identical recombination sites. (See, e.g., column 2, lines 40-51.)

Baszczynski et al. further teaches that the nucleotide sequence flanked by recombination sites in the second nucleic acid molecule can comprise any of a variety of genes to be expressed in the plant. (See, e.g., the second full paragraph in column 7.) Baszczynski et al. teaches, "In one embodiment of the invention...the nucleotide sequence may be inserted into a site within the genome which is 3' to a promoter region. In this latter instance the insertion of the coding sequence 3' to the promoter region is such that a functional expression unit is achieved upon integration." (Column 7, lines 37-44.) Thus Baszczynski et al. teaches an embodiment of the method wherein the method results in excision of a sequence in the second nucleic acid molecule that is located between the signal sequences (i.e., the gene of interest) and the excision results in

modulation of expression of the target gene (i.e., by its insertion 3' of a promoter comprised by the second nucleic acid molecule.)

The method of Baszczynski et al. comprises all of the elements of the instant claims except Baszczynski et al. does not teach that the first nucleic acid molecule comprises the recombinase and that the recombinase, when expressed in the cell, excises a sequence in the first nucleic acid molecule that is located between the signal sequences and excision results in modulation of expression of the recombinase gene.

However, Baszczynski et al. teaches that any means known in the art for bringing the three components of the system together may be used in the invention and contemplates embodiments wherein the first and second nucleic acid molecules as well as a gene encoding the recombinase may be stably integrated into the genome and teaches that the components of the system might be brought together by crossing transformed plants comprising each of the three components. (See especially the fifth and sixth full paragraphs in column 6.)

Qin et al. teaches a method for exchanging nucleic acids within transformed plants wherein a transformed plant comprising a cre recombinase operably linked to a promoter sequence (hereinafter referred to as the "first nucleic acid molecule") is crossed with a transformed plant comprising a promoterless target gene of interest (hereinafter referred to as the second nucleic acid molecule). As contemplated in the method of Baszczynski et al., the recombinase site in the first and second nucleic acid molecules of Qin et al. are positioned such that recombination places the target gene under the control of the promoter, thereby modulating expression of the target gene and separates the recombinase gene from the promoter thereby

modulating expression of the recombinase gene. (See especially the paragraph bridging the left and right columns on page 1707, Figure 1 and the caption thereto.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the first and second nucleic acid molecules used in the method of Baszczynski et al. such that the first nucleic acid molecule comprises a recombinase gene located such that the recombination event separates the coding sequence from its promoter, thereby extinguishing recombinase expression as taught in the method of Qin et al. As described above, Baszczynski et al. teaches configuration of the target gene such that recombination places the target gene under the control of a promoter located in the first nucleic acid molecule, teaches that each of the components of the system might be integrated into the plant genome and teaches that the components can be contacted by crossing transformed plants. Qin et al. teaches a similar method with the added feature of the recombinase situated in the first nucleic acid molecule such that recombination extinguishes expression of the recombinase. As evidenced by the highly technical nature of the art (i.e., recombinant DNA technology), the level of skill in the art is very high. Furthermore, one of skill in the art would be aware that site-specific recombination via lox or frt recombination sites is reversible and, therefore, minimizing undesirable reverse recombination events by extinguishing the recombinase after the recombination event has occurred is an improvement over methods wherein recombinase expression remains. Therefore, the claimed invention, as a whole, would have been obvious because the method of enhancing strand exchange recombination in plants *in vivo* by configuring the nucleic acid molecules such that recombinase expression is extinguished was made part of the ordinary capabilities of one skilled in the art based on the teaching of such improvement by Qin et al. One of ordinary skill in

the art would have been capable of applying this known method of enhancement to the method of Baszczynski et al. and the results would have been predictable to one of ordinary skill in the art.

In view of the foregoing, the method of the instant claim 6, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made. Furthermore, the limitations of the dependent claims are also found in the teachings of Baszczynski et al. and Qin et al. As described above, the prior art method is practiced in plants according to the limitations of the instant claim 12. Furthermore, Baszczynski et al. contemplates an embodiment wherein the target gene effects plant susceptibility to disease, which renders obvious the disease resistance gene of claim 13 and signal sequences in the second nucleic acid molecule that are in direct orientation with respect to one another according to claim 17 (see, e.g., Figure 1). Placement of the recombinase gene within the first nucleic acid molecule would result in a structure wherein the signal sequences flank the recombinase according to the limitations of claim 21. The first and second nucleic acid molecules of the prior art methods are on separate vectors according to the instant claim 24 and the prior art contemplates both the cre/lox and Flp/FRT recombination systems according to the limitations of the instant claim 25.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baszczynski et al. (*supra*) in view of Qin et al. (*supra*) as applied to claim 12 herein above and further in view of Fitzmaurice et al. WO 93/07257.

Claims 15 and 16 are directed to the method of claim 12 wherein the recombinase is expressed in a fruit and not expressed in a tissue that is not a fruit. As described above, the

teachings of Baszczynski et al. in view of Qin et al. render obvious the method of claim 12 as a whole. The art does not teach the method wherein the recombinase is expressed in fruit of the plant but not in a tissue that is not a fruit. Baszczynski et al. does teach, however, that the method can be practiced in a tomato plant. (See especially column 9, line 54.) Fitzmaurice et al. teaches tomato fruit specific promoters. (See especially the "Summary of the Invention" beginning on page 2.) In Example 5, beginning on page 16, Fitzmaurice et al. demonstrate the capacity of the promoter to express a heterologous gene. Fitzmaurice et al. goes on to teach the advantages of tissue specific expression, which allows for the phenotype of a particular plant part to be modified without requiring that the product be produced in all tissues, which may result in various adverse effects on the growth, health, and production capabilities of the plant. (Page 17 paragraph 3.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to practice the method of Baszczynski et al. in view of Qin et al. wherein the recombinase gene is operably linked to a fruit specific promoter. In *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007), the Supreme Court particularly emphasized "the need for caution in granting a patent based on a combination of elements found in the prior art," (*Id.* At 1395) and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on it precedent that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." (*Id.* At 1395.) In the instant case, the prior art included each element of the claimed invention with the only difference being the actual combination of the elements in a single prior art reference. One skilled in the art could have

combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of invention. Furthermore, advantages of tissue specific expression, such as the avoidance of adverse effects resulting from production of the heterologous protein in all plant tissues, would have motivated one of skill in the art at the time the invention was made to use a tissue specific promoter such as the promoter of Fitzmaurice et al. Therefore, the claimed invention, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made.

Claims 6, 17-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson *et al.*, US Patent No. 5,629,159 (made of record in the IDS filed 26 February 2004).

The limitations of independent claim 6 are described herein above.

Throughout the specification, Anderson describes methods for creating a conditionally immortalized cell comprising providing an expression vector comprising a target gene and site specific recombination sequences, wherein expression of the target gene is regulated by inducing recombination at the site specific recombination sequences (see especially the "SUMMARY OF THE INVENTION" section bridging col. 1-2). In one embodiment, Anderson contemplates introducing the vectors shown in Figure 6B, which comprises the following elements:

FIG._6B

Wherein "RTS" stands for recombinase target sites. The vector of Anderson comprises all of the elements of the first and second nucleic acid molecule of claim 6 except that the same signal sequences are used to excise both the first and second nucleic acid molecule. That is, Anderson does not teach that the signal sequences for the first nucleic acid and the second nucleic acid are not the same sequences. However, the difference between the construct used in the claims of the instant application and the construct used in the method of Anderson et al. amount to no more than a duplication of parts which would have no effect on the actual functioning of the method as described by Anderson et al. Specifically, if one were to include additional RTS flanking the recombinase gene in the 6B construct shown above, expression of the recombinase gene would result in excision of the same elements from the genome and would have exactly the same functional effects as in the method practiced without additional RTSs flanking the recombinase gene. In *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. (Claims at issue were directed to a water-tight masonry structure wherein a water seal of flexible material fills the joints which form between adjacent pours of concrete. The claimed water seal has a "web" which lies in the joint, and a plurality of "ribs" projecting outwardly from each side of the web into one of the adjacent concrete slabs. The prior art disclosed a flexible water stop for preventing passage of water between masses of concrete in the shape of a plus sign (+). Although the reference did not disclose a plurality of ribs, the court held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced.). As in *Harza* the claims of the instant application differ from the prior art only by virtue of a duplication of an element (i.e., the RTS). As the duplication of parts does not

produce a new and unexpected result, the instant claims are not patentable over the teachings of the prior art.

Furthermore, Anderson contemplates the method wherein the RTS sequences are configured to provide excision of intervening sequences when contacted with a recombinase (see, *e.g.*, the paragraph bridging columns 6-7), which the skilled artisan would understand requires that the RTS sequences be in direct orientation with respect to one another according to claim 17. According to Figure 6B, if the target gene is "immortalization gene" the site specific recombination sites flank the target gene so that expression of the recombinase results in excision of the target gene and inactivation of expression of the target gene according to claim 18, and wherein the site specific recombination sites also flank the positive regulatory element (*i.e.*, the promoter) of the target gene so that expression of the recombinase also results in excision of the positive regulatory element according to claim 19. Likewise, in the vector of Anderson the signal sequences flank the recombinase gene and its positive regulatory element according to claims 21 and 22.

Claim 20, recites that the signal sequences in the second nucleic acid molecule flank a negative regulatory element of the target gene so that expression of the recombinase results in excision of the negative regulatory element and activation of expression of the target gene. According to Figure 6B, if one defines the target gene as the "second selection gene" the site specific recombination sites flank the "stop" signal (a negative regulatory element preventing expression of the "second selection gene") and expression of the recombinase results in excision of the negative regulatory element and activation of expression of the second selection gene.

Finally, the first and second nucleic acid molecules of Anderson are present in the same vector according to claim 23 and the recombinase systems can be the cre/lox system or Flp/FRT system according to claim 25 (see especially col. 4, ¶4).

Claims 6, 17-22, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson *et al.* (*supra*) in view of von Melchner et al. WO 97/07223.

The limitations of the instant claim 6 are described herein above.

Throughout the specification, Anderson describes methods for creating a conditionally immortalized cell comprising providing an expression vector comprising a target gene and site specific recombination sequences, wherein expression of the target gene is regulated by inducing recombination at the site specific recombination sequences (see especially the "SUMMARY OF THE INVENTION" section bridging col. 1-2). In one embodiment, Anderson contemplates introducing the vectors shown in Figure 1C, which comprises the following elements:

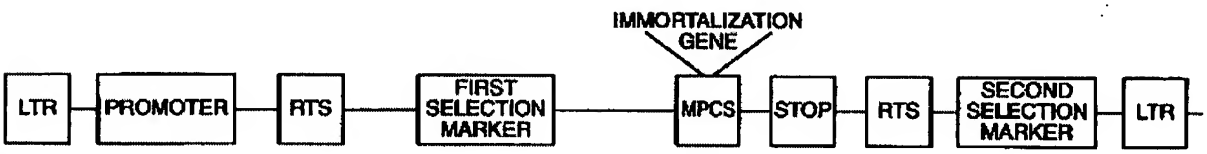

FIG._1C

Wherein "RTS" stands for recombinase target sites. The vector of Anderson comprises all of the elements of the instant second nucleic acid molecule. In the first and second full paragraphs in column 8 of the instant application, *inter alia*, Anderson further contemplates inducing recombination of the second nucleic acid molecule by introducing a nucleic acid

molecule encoding a recombinase, which is preferably expressed transiently and might be introduced using a retroviral vector. Anderson teaches that transient expression is achieved by methods known in the art.

Thus, Anderson et al. teaches a method that is the same as the method presently claimed except that Anderson et al. does not teach that transient recombinase expression is achieved by self-excision of the recombinase gene. von Melcher et al. teaches methods of using recombinases to excise unwanted elements of vectors similar to that of Anderson et al., wherein recombinase expression is limited by self-excision of the recombinase gene. (See especially Figure 4 and the caption thereto.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the retroviral vector comprising a self-excising recombinase gene as taught by von Melcher et al. as the retroviral vector used to introduce a recombinase gene according to the method of Anderson et al. All of the elements of the invention presently claimed were known in the art at the time the instant invention was made, and Anderson et al. teaches a method that differs from the method presently claimed only in that Anderson et al. does not specifically identify introducing a self-excising recombinase on a separate retroviral vector—although Anderson et al. does contemplate introducing a transiently expressed recombinase on a separate retroviral vector. von Melcher et al. teaches that retroviral vectors comprising self-excising recombinases were known in the art at the time the invention was made and used in methods similar to the method described by Anderson et al. Furthermore, one could have combined the elements of the prior art at the time the invention was made with predictable results. Therefore,

the invention of independent claim 6 as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made in view of the teachings of the prior art.

Furthermore, Anderson contemplates the method wherein the RTS sequences are configured to provide excision of intervening sequences when contacted with a recombinase (see, *e.g.*, the paragraph bridging columns 6-7), which the skilled artisan would understand requires that the RTS sequences be in direct orientation with respect to one another according to claim 17. According to Figure 1C, if the target gene is "immortalization gene" the site specific recombination sites flank the target gene so that expression of the recombinase results in excision of the target gene and inactivation of expression of the target gene according to claim 18, and wherein the site specific recombination sites also flank the positive regulatory element (*i.e.*, the promoter) of the target gene so that expression of the recombinase also results in excision of the positive regulatory element according to claim 19. In the vector of von Melcher, the signal sequences flank the recombinase gene and its positive regulatory element according to claims 21 and 22.

Claim 20, recites that the signal sequences in the second nucleic acid molecule flank a negative regulatory element of the target gene so that expression of the recombinase results in excision of the negative regulatory element and activation of expression of the target gene. According to Figure 1C, if one defines the target gene as the "second selection gene" the site specific recombination sites flank the "stop" signal (a negative regulatory element preventing expression of the "second selection gene") and expression of the recombinase results in excision of the negative regulatory element and activation of expression of the second selection gene.

Finally, the first and second nucleic acid molecules of Anderson in view of von Melcher et al. are present on separate vectors according to claim 24 and the recombinase systems can be the cre/lox system or Flp/FRT system according to claim 25 (see especially col. 4, ¶4).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel M Sullivan/
Primary Examiner
Art Unit 1636